



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

9701 '00 OCT 25 P2:22

OCT 24 2000

Karen A. Rocco
Director, Regulatory Affairs
Zenith Goldline Pharmaceuticals
140 Legrand Avenue
Northvale, New Jersey 07647

Dear Ms. Rocco:

This is in response to your letters of October 4, 2000 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Zenith Goldline Pharmaceuticals, is making the following claims, among others, for the products below:

Cholesterol Formula Tablets

"Helps maintain healthy cholesterol levels."

Evening Primrose Oil Softgels

"Promotes healthy cholesterol levels."

Fish Oil Concentrate Softgels

"Helps maintain healthy cholesterol levels."

Garlic Oil Softgels

"Helps maintain healthy cholesterol levels."

Green Tea Extract Softgels

"Helps maintain healthy cholesterol levels."

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for these products suggest that they are intended to treat, prevent, cure, or mitigate diseases. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

975-0163

LET412

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Please contact us if we may be of further assistance.

Sincerely,

John B. Foret
Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling,
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

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Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

FDA, New Jersey District Office, Office of Compliance, HFR-MA340

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-800 (r/f, file)

HFS-810

HFS-811 (file)

HFD-40 (Behrman)

HFD-310

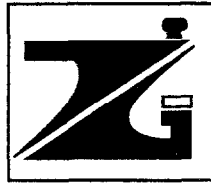
HFD-314 (Aronson)

HFS-605

HFV-228 (Benz)

GCF-1 (Dorsey, Nickerson)

f/t:HFS-811:afp:10/19/00:72820:disc1



Zenith Goldline
P H A R M A C E U T I C A L S

Regulatory Affairs

October 4, 2000

Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, SW (HFS-450)
Washington, D.C. 20204

Dear Sir or Madam:

This letter will serve as a 30 day notification pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994 that Zenith Goldline Pharmaceuticals, Inc. is using the following statement on our Cholesterol formula tablets supplement under one or more of the following brand names:

"Goldline", "Goldline Naturals™", "PharmaSelect":

Helps maintain healthy cholesterol levels

The above statement is accompanied by the required disclaimer pursuant to Section 6 of the Dietary Supplement Health and Education Act.

Sincerely,

ZENITH GOLDLINE PHARMACEUTICALS, INC.

Karen A. Rocco, RAC
Director, Global Regulatory Affairs



Zenith Goldline

P H A R M A C E U T I C A L S

Regulatory Affairs

October 4, 2000

Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, SW (HFS-450)
Washington, D.C. 20204

Dear Sir or Madam:

This letter will serve as a 30 day notification pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994 that Zenith Goldline Pharmaceuticals, Inc. is using the following statement on our Evening primrose oil softgels 500 mg supplement under one or more of the following brand names:

“Goldline”, “Goldline Naturals™”, “PharmaSelect”:

Promotes healthy cholesterol levels

The above statement is accompanied by the required disclaimer pursuant to Section 6 of the Dietary Supplement Health and Education Act.

Sincerely,

ZENITH GOLDLINE PHARMACEUTICALS, INC.

Karen A. Rocco, RAC
Director, Global Regulatory Affairs



Zenith Goldline

P H A R M A C E U T I C A L S

Regulatory Affairs

October 4, 2000

Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, SW (HFS-450)
Washington, D.C. 20204

Dear Sir or Madam:

This letter will serve as a 30 day notification pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994 that Zenith Goldline Pharmaceuticals, Inc. is using the following statement on our Fish oil concentrate softgels 1000 mg supplement under one or more of the following brand names:

"Goldline", "Goldline Naturals™", "PharmaSelect":

Helps maintain healthy cholesterol levels

The above statement is accompanied by the required disclaimer pursuant to Section 6 of the Dietary Supplement Health and Education Act.

Sincerely,

ZENITH GOLDLINE PHARMACEUTICALS, INC.

Karen A. Rocco, RAC
Director, Global Regulatory Affairs



Zenith Goldline
P H A R M A C E U T I C A L S

Regulatory Affairs

October 4, 2000

Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, SW (HFS-450)
Washington, D.C. 20204

Dear Sir or Madam:

This letter will serve as a 30 day notification pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994 that Zenith Goldline Pharmaceuticals, Inc. is using the following statement on our Garlic oil softgels 3 mg supplement under one or more of the following brand names:

"Goldline", "Goldline Naturals™", "PharmaSelect":

Helps maintain normal cholesterol levels

The above statement is accompanied by the required disclaimer pursuant to Section 6 of the Dietary Supplement Health and Education Act.

Sincerely,

ZENITH GOLDLINE PHARMACEUTICALS, INC.

Karen A. Rocco, RAC
Director, Global Regulatory Affairs



Zenith Goldline

P H A R M A C E U T I C A L S

Regulatory Affairs

October 4, 2000

Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, SW (HFS-450)
Washington, D.C. 20204

Dear Sir or Madam:

This letter will serve as a 30 day notification pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994 that Zenith Goldline Pharmaceuticals, Inc. is using the following statement on our Green tea extract softgels 100 mg supplement under one or more of the following brand names:

“Goldline”, “Goldline Naturals™”, “PharmaSelect”:

Antioxidant support. Helps maintain a healthy cholesterol profile.

The above statement is accompanied by the required disclaimer pursuant to Section 6 of the Dietary Supplement Health and Education Act.

Sincerely,

ZENITH GOLDLINE PHARMACEUTICALS, INC.

Karen A. Rocco, RAC
Director, Global Regulatory Affairs